

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

PEDRO URENA, on behalf of himself and all
others similarly situated,

Plaintiff,

v.

E25BIO INC.,

Defendant.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Pedro Urena (“Plaintiff”) brings this action on behalf of himself and all others similarly situated against Defendant E25Bio Inc. (“E25Bio” or “Defendant”). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendant’s manufacturing, distribution, and sale of E25Bio COVID-19 Direct Antigen Rapid Tests, also known as E25Bio SARS-CoV-2 Antigen Test Kits (the “Covid Tests”) that are highly inaccurate and falsely labeled as claiming to be authorized by the Food & Drug Administration (“FDA”).

2. As the COVID-19 pandemic enters its third year, consumers have sought a convenient and easy way to test for COVID-19 rather than having to schedule an appointment at

a clinic. This demand has only increased in the wake of the Omicron variant of the virus, which has infected a record number of Americans.¹

3. To fulfill this need, a number of companies have developed at-home rapid COVID-19 tests. These at-home rapid tests are supposed to provide a consumer with quick and accurate results from the convenience of the consumer's home, rather than waiting several days for a test result from a clinic.²

4. Defendant claims to provide such a service. A Cambridge, Massachusetts-based start-up that develops diagnostic tests for infectious diseases like dengue and Zika, Defendant raised \$2 million from investors to specifically develop and manufacture the Covid Tests.³

5. On each package of the Covid Tests, Defendant represents that the Covid Tests are "[r]apid test[s] for the detection of Coronavirus CoV Spike and nucleoprotein antigen," and that the tests are issued pursuant to an "Emergency Use Authorization (EUA) USA FDA":

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¹ See Hannah Kuchler et al., *Covid Rapid Test Makers Race To Meet Overwhelming Global Demand*, FINANCIAL TIMES, Jan. 21, 2022, <https://www.ft.com/content/f3eeefc-62a5-4a50-997c-e478456bd56f>.

² SELF-TESTING AT HOME OR ANYWHERE, <https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html>.

³ Shivangi Misra, *Biotech Startup With Mit Tata Center Roots Produces 15-Minute Tests For Covid-19*, MITEI, Apr. 16, 2020, <https://energy.mit.edu/news/mit-tata-center-startup-e25bio-produces-15-minute-tests-for-covid-19/>.



6. On its website, Defendant promises consumers that its “novel technology has better accuracy than ‘gold standard’ PCR without the need for equipment and at a fraction of the cost and time.”⁴ “PCR” refers to polymerase chain reaction test, which is generally considered the most accurate test for COVID-19.⁵ By contrast, most rapid tests, including Defendant’s, are “antigen tests.” Defendant thus represents on its website that its Covid Tests are more accurate than PCR tests, which are considered the most accurate test of all.

⁴ E25Bio’s NOVEL TECHNOLOGY IS EXCLUSIVELY LICENSED FROM MIT, <https://www.e25bio.com/technology>.

⁵ Carrie MacMillan, *Which COVID-19 Test Should You Get?*, YALE MEDICINE, Jan. 20, 2022, <https://www.yalemedicine.org/news/which-covid-test-is-accurate>.

7. Defendant further represents on its website that “[f]or our antigen tests, such as COVID-19 ... we use a high-throughput screening platform to identify antibody pairs that can accurately target proteins using nanotechnology.”

8. Once consumers conduct the test, they can “track, monitor, and share disease information in real time” using Defendant’s digital platform.

9. Unfortunately for consumers, these representations are false. On February 4, 2022, the FDA warned consumers “not to use the E25Bio COVID-19 Direct Antigen Rapid Test” due to the risk of false results “because E25Bio has not provided the FDA with adequate data demonstrating that the test’s performance is accurate.” The FDA also instructed physicians to retest patients who were previously tested with the Covid Tests due to the risk of inaccurate results.⁶

10. Specifically, the FDA set guidelines for at-home tests, requiring that at-home tests reach “90% overall sensitivity—that is, antigen tests would pick up nine out of ten positive tests that a PCR identified.”⁷ Defendant’s tests did not meet this standard. On the contrary, in a comparative study of six at-home tests, five of the six tests “showed high specificity ($\geq 98.0\%$),” while the sixth test—Defendant’s Covid Tests—show only 86.0% specificity.⁸ In other words,

⁶ DO NOT USE E25BIO COVID-19 TESTS: FDA SAFETY COMMISSION, <https://www.fda.gov/medical-devices/safety-communications/do-not-use-e25bio-covid-19-tests-fda-safety-communication>.

⁷ Lydia DePillis, *This Scientist Created a Rapid Test Just Weeks Into the Pandemic. Here’s Why You Still Can’t Get It*, PROPUBLICA, Dec. 21, 2021, <https://www.propublica.org/article/this-scientist-created-a-rapid-test-just-weeks-into-the-pandemic-heres-why-you-still-cant-get-it>.

⁸ Suzanne Pickering et al., *Comparative Performance Of Sars-Cov-2 Lateral Flow Antigen Tests And Association With Detection Of Infectious Virus In Clinical Specimens: A Single-Centre Laboratory Evaluation Study*, 2 LANCET MICROBE 461, 461 (2021), <https://www.thelancet.com/action/showPdf?pii=S2666-5247%2821%2900143-9>.

the Covid Tests failed to meet the FDA's bar for accuracy and are significantly less accurate than other at-home COVID-19 tests.

11. The FDA also noted that "[t]his test has not been authorized, cleared, or approved by the FDA for distribution or use in the United States, and it may include false labeling representing that the test is authorized by the FDA."

12. When Plaintiff purchased Defendant's Covid Tests, Plaintiff did not know, and had no reason to know, that Defendant's Covid Tests were not accurate, and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus illegally sold). Not only would Plaintiff not have purchased Defendant's Covid Tests at all had he known the foregoing information, but he would also not have been capable of purchasing them, as the Covid Tests were not cleared for distribution in the United States.

13. Moreover, no reasonable consumer would pay for COVID-19 tests that do not provide accurate results. Consumers reasonably expect that COVID-19 tests are designed to provide accurate results so that they can plan accordingly based upon those results. And, as the FDA notes, both false negatives and false positives are injurious. A "false negative" "can [] lead to further spread of the SARS-CoV-2 virus, including when people are housed together in health care, long-term care, and other facilities based on these false test results" because someone who presumes he or she is negative may not take the recommended safety precautions. And a "false positive" "may lead to a delay in both the correct diagnosis and appropriate treatment for the actual cause of a person's illness, which could be another life-threatening disease that is not COVID-19. False-positive results could also lead to further spread of the SARS-CoV-2 virus when presumed positive people are housed together."

14. Thus, if Plaintiff and Class members had been informed that Defendant's Covid Tests were not accurate, authorized, cleared, nor approved by the FDA for distribution or use in the United States (and thus were unlawfully sold), they would not have purchased or used the Products at all, or would have paid significantly less for the Products, making such omitted facts material to them.

15. Plaintiff and Class members were injured by the full purchase price of the Covid Tests because the Covid Tests are worthless and inaccurate, are not approved by the FDA, and have been illegally distributed. *See Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *see also In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021) ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for.").

16. Plaintiff and Class members bargained for COVID-19 tests that were accurate, approved by the FDA, and were legally sold, and were deprived the basis of their bargain when Defendant sold Covid Tests that did not match the aforementioned criteria.

17. Plaintiff and Class members are further entitled to damages for the monies paid to purchase the Covid Tests, statutory and punitive damages, attorneys' fees and costs, and injunctive relief.

18. On February 18, 2022, the FDA announced that Defendant had issued a "recall" of the Covid Tests. The recall notice stated that "this test was not authorized, cleared, or

approved by the FDA, there is not sufficient data demonstrating that the test's performance is accurate. This means there is a risk of both false-negative and false-positive test results.”⁹

However, the recall is deficient in numerous respects, including but not limited to the following:

- A. The recall does not promise to refund consumers. Instead, the recall notice simply states “[c]omplete and return a form enclosed with the letter to indicate the number of destroyed tests and the date in which the destruction of the tests took place.”
- B. The recall period is limited to “September 2020 to November 2021,” even though tests sold before and after that time period (including Plaintiff’s January 2022 test) suffered from the same issues.
- C. Defendant did not adequately publicize the refund remedy, only sending out letters to “customers and distributors.” However, there is a significant risk that such letters could be discarded, and there is no information about the recall on Defendant’s website. Nor can consumers fill out the aforementioned form on Defendant’s website.
- D. Even if the recall offered a full refund (and it does not), the recall does not fully compensate consumers in states like New York, where consumers are entitled to statutory damages above the purchase price of the Covid Tests under New York’s consumer protection laws.

⁹ E25BIO RECALLS COVID-19 DIRECT ANTIGEN RAPID TESTS THAT ARE NOT AUTHORIZED, CLEARED, OR APPROVED BY THE FDA AND MAY GIVE FALSE RESULTS, https://www.fda.gov/medical-devices/medical-device-recalls/e25bio-recalls-covid-19-direct-antigen-rapid-tests-are-not-authorized-cleared-or-approved-fda-and?utm_medium=email&utm_source=govdelivery.

19. Plaintiff brings this action on behalf of himself and the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) violation of New York General Business Law (“GBL”) § 349; (iii) violation of GBL § 350; (iv) fraud; and (v) unjust enrichment.

PARTIES

20. Plaintiff Pedro Urena is a resident of The Bronx, New York and has an intent to remain there, and is therefore a domiciliary of New York. In or about January 2022, Mr. Urena purchased Defendant’s Covid Test from a Rite Aid in The Bronx for approximately \$25. When purchasing the Covid Test, Mr. Urena reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the Covid Test was accurate and authorized, cleared, and approved by the FDA for distribution and use in the United States. Mr. Urena relied on these representations and warranties in deciding to purchase the Covid Test manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Covid Test from Defendant if he had known that it was not, in fact, accurate and authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, was illegally sold). Mr. Urena took Defendant’s Covid Test and received a positive result. He then went to a local clinic and received a PCR test, which was negative. Mr. Urena therefore received a “false positive” from Defendant’s Covid Test.

21. Defendant E25Bio Inc. is a Delaware corporation with its headquarters at 501 Massachusetts Avenue, Cambridge, Massachusetts 01239. E25Bio distributes the Covid Tests throughout the United States and the State of New York. The Covid Tests, including the Covid

Test purchased by Plaintiff and members of the putative Class, are available at retail stores throughout New York and the United States.

JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds \$5,000,000 exclusive of interest and costs.

23. This Court has personal jurisdiction over Defendant because Plaintiff purchased the Covid Test in this District and Defendant conducts significant business in this District.

24. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claim occurred in this District.

CLASS ACTION ALLEGATIONS

25. Plaintiff seeks to represent a class defined as all persons in the United States who purchased the Covid Tests (the “Class”).

26. Plaintiff also seeks to represent a subclass of all Class members who purchased the Covid Tests in New York (the “Subclass”).

27. The Class and Subclass are collectively referred to as the “Classes.”

28. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Classes may be expanded or narrowed by amendment to the complaint or narrowed at class certification.

29. Specifically excluded from the Classes are Defendant, Defendant’s officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees,

principals, servants, partners, joint ventures, or entities controlled by Defendant, and its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

30. **Numerosity.** The members of the proposed Classes are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of individuals that are members of the proposed Classes. Although the precise number of proposed members is unknown to Plaintiff, the true number is known by Defendant. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

31. **Typicality.** The claims of the representative Plaintiff are typical of the claims of the Classes in that the representative Plaintiff, like all members of the Classes, purchased the Covid Tests, which were worthless because they were inaccurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold). The representative Plaintiff, like all members of the Classes, has been damaged by Defendant's misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendant's misconduct are common to all members of the Classes and represent a common thread of misconduct resulting in injury to all members of the Classes.

32. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individual members of the Classes. These common legal and factual questions include, but are not limited to, the following:

- (a) whether the Covid Tests manufactured by Defendant were inaccurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold), thereby breaching the express warranties made by Defendant;
- (b) whether Defendant knew or should have known the Covid Tests were inaccurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold), thereby constituting fraud and/or fraudulent concealment;
- (c) whether Defendant is liable to Plaintiff and the Classes for unjust enrichment;
- (d) whether Defendant is liable to Plaintiff and the Classes for fraud;
- (e) whether Plaintiff and the Classes have sustained monetary loss and the proper measure of that loss;
- (f) whether Plaintiff and the Classes are entitled to declaratory and injunctive relief;
- (g) whether Plaintiff and the Classes are entitled to restitution and disgorgement from Defendant; and
- (h) whether the marketing, advertising, packaging, labeling, and other promotional materials for the Covid Tests are deceptive.

33. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Classes. Plaintiff has retained counsel who are highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Classes. Plaintiff has no interests that are antagonistic to those of the Classes.

34. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by members of the Classes are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for members of the Classes, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Classes could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

35. In the alternative, the Classes may be certified because:

- (a) the prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudication with respect to individual members of the Classes that would establish incompatible standards of conduct for the Defendant;
- (b) the prosecution of separate actions by individual members of the Classes would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Classes not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or
- (c) Defendant has acted or refused to act on grounds generally applicable to the Classes as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I

Breach Of Express Warranty

36. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

37. Plaintiff brings this claim individually and behalf of the members of the proposed Classes against Defendant.

38. In connection with the sale of the Covid Tests, Defendant, as the designer, manufacturer, marketer, distributor, and/or seller issued written warranties by representing that the Covid Tests were accurate and authorized, cleared, and approved by the FDA for distribution and use in the United States (and thus, legally sold).

39. As a direct and proximate cause of Defendant's breach of express warranty, Plaintiff and the Classes have been injured and harmed because they would not have purchased the Covid Tests on the same terms if they knew that the Covid Tests were inaccurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold).

40. On February 15, 2022, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiff that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an express warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit 1**.

COUNT II
Violation Of New York General Business Law § 349

41. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

42. Plaintiff brings this claim individually and on behalf of the members of the proposed Subclass against Defendant.

43. GBL § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

44. In its sale of goods throughout the State of New York, Defendant conducts business and trade within the meaning and intendment of GBL § 349.

45. Plaintiff and members of the Subclass are consumers who purchased the Covid Tests from Defendant for their personal use.

46. By the acts and conduct alleged herein, Defendant has engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the Covid Tests were (i) accurate, and (ii) authorized, cleared, and approved by the FDA for distribution and use in the United States (and thus, legally sold). Defendant also materially omitted key facts regarding the true nature of the Covid Tests, specifically that the Covid Tests were not accurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold). Had Plaintiff and members of the Subclass been apprised of these facts, they would have been aware of them and would not have purchased the Covid Tests.

47. The foregoing deceptive acts and practices were directed at consumers.

48. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the Covid Tests to

induce consumers to purchase the same. No reasonable consumer would knowingly purchase a COVID-19 test that was inaccurate and bore a significant risk of a “false positive” or “false negative.” Further, no reasonable consumer would knowingly purchase a COVID-19 test that was not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold).

49. By reason of this conduct, Defendant engaged in deceptive conduct in violation of GBL § 349.

50. Defendant’s actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of Subclass have sustained from having paid for and used Defendant’s Covid Tests.

51. As a result of Defendant’s violations, Plaintiff and members of the Subclass have suffered damages because: (a) they paid a price premium in the amount of the full purchase price of the Covid Tests based on Defendant’s deceptive conduct; and (b) the Covid Tests do not have the characteristics, uses, benefits, or qualities as promised.

52. On behalf of himself and other members of the Subclass, Plaintiff seeks to recover his actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys’ fees.

COUNT III
Violation Of New York General Business Law § 350

53. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

54. Plaintiff brings this claim individually and on behalf of the members of the proposed Subclass against Defendant.

55. GBL § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

56. Pursuant to said statute, false advertising is defined as “advertising, including labeling, of a commodity ... if such advertising is misleading in a material respect.”

57. Based on the foregoing, Defendant has engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of GBL § 350.

58. Defendant’s false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

59. Defendant’s false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

60. Defendant’s false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

61. Defendant also materially omitted key facts regarding the true nature of the Covid Tests, specifically that the Covid Tests were not accurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold). Had Plaintiff and members of the Subclass been apprised of these facts, they would have been aware of them and would not have purchased the Covid Tests.

62. As a result of Defendant’s false, misleading, and deceptive statements and representations of fact, Plaintiff and the Subclass have suffered and continue to suffer economic injury.

63. As a result of Defendant's violations, Plaintiff and members of the Subclass have suffered damages due to said violations because: (a) they paid a premium price in the amount of the full purchase price of the Covid Tests based on Defendant's deceptive conduct; and (b) the Covid Tests do not have the characteristics, uses, benefits, or qualities as promised.

64. On behalf of himself and other members of the Subclass, Plaintiff seeks to recover actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Fraud

65. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

66. Plaintiff brings this claim individually and on behalf of the members of the Classes against Defendant.

67. Defendant made fraudulent misrepresentations to Plaintiff and members of the Classes regarding the Covid Tests, specifically that the Covid Tests were accurate and were authorized, cleared, and approved by the FDA for distribution and use in the United States (and thus, legally sold). Defendant also materially omitted facts from Plaintiff and members of the Classes, including that the Covid Tests in fact were not accurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold).

68. Defendant had a duty to disclose material facts to Plaintiff and the Classes given their relationship as contracting parties and intended users of the Covid Tests. Defendant also had a duty to disclose material facts to Plaintiff and the Classes, namely that it was in fact manufacturing, distributing, and selling COVID-19 tests that were not accurate and were

illegally sold, because Defendant had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

69. Defendant knew or should have known that the Covid Tests were not accurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold), but continued to manufacture and sell the Covid Tests nonetheless. The FDA regularly authorizes COVID-19 tests by manufacturers that send proper documentation.¹⁰ As alleged above, Defendant knew that its testing data was not sufficiently accurate to support FDA approval of the Covid Tests, but nonetheless represented the Covid Tests were accurate and were authorized, cleared, and approved by the FDA for distribution and use in the United States (and thus, legally sold) demonstrates scienter. During this time, Plaintiff and members of the Classes were using the Covid Tests without knowing the Covid Tests were inaccurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold).

70. Defendant failed to discharge its duty to disclose these material facts.

71. In so failing to disclose these material facts to Plaintiff and the Classes, Defendant intended to hide from Plaintiff and the Classes that they were purchasing and using Covid Tests that were not accurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold), and thus acted with scienter and/or an intent to defraud.

72. Plaintiff and the Classes reasonably relied on Defendant's representations and omissions insofar as they would not have purchased the Covid Tests manufactured and sold by

¹⁰ COVID-19 TESTS AND COLLECTION KITS AUTHORIZED BY THE FDA: INFOGRAPHIC, <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-tests-and-collection-kits-authorized-fda-infographic>.

Defendant had they known the Covid Tests were not accurate and were not authorized, cleared, or approved by the FDA for distribution or use in the United States (and thus, illegally sold).

73. As a direct and proximate cause of Defendant's fraudulent misrepresentations and omissions, Plaintiff and the Classes suffered damages in the amount of monies paid for the defective Covid Tests.

74. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT V
Unjust Enrichment

75. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

76. Plaintiff brings this claim individually and on behalf of the members of the Classes against Defendant.

77. Plaintiff and the Classes conferred a benefit on Defendant in the form of monies paid to purchase Defendant's worthless and illegally sold Covid Tests.

78. Defendant voluntarily accepted and retained this benefit.

79. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for Covid Tests that were inaccurate and illegally sold, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests, individually and on behalf of the alleged Classes, that the Court enter judgment in their favor and against Defendant as follows:

- (a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as the representative of the Classes, and naming Plaintiff's attorneys as Class Counsel;

- (b) For an order declaring that Defendant's conduct violates the causes of action referenced herein;
- (c) For an order finding in favor of Plaintiff and the Classes on all counts asserted herein;
- (d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;
- (e) For prejudgment interest on all amounts awarded;
- (f) For an order of restitution and all other forms of equitable monetary relief;
- (g) For injunctive relief as pleaded or as the Court may deem proper; and
- (h) For an order awarding Plaintiff and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable as of right.

Dated: February 18, 2022

Respectfully Submitted,

BURSOR & FISHER, P.A

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